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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

1655

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/785,444

Applicant(s)

YUAN ET AL.

Examiner

Christopher R. Tate

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1204 & 0205</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-19 are presented for examination on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Chang et al. (Am J. Chin. Med., 2002).

A pharmaceutical composition comprising a water extract from the leaves of *Toona sinensis* and a pharmaceutical carrier is claimed.

Chang et al. teach an anti-cancer (pharmaceutical) composition comprising the centrifuged supernatant of a water extract of *Toona sinensis* leaves (see, e.g., page 308 under the heading *Preparation of Extract of Toona sinensis Roemor*). Please note that the water within the supernatant preparation is well known and accepted in the art as reading upon a pharmaceutical carrier.

Therefore, the reference is deemed to anticipate the instant claim above.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1655

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 16-19 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hsu et al. (Kaohsiung J. Med. Sci, 2003).

The claims are drawn to an extract from the leaves of *Toona sinensis*, and a pharmaceutical composition comprising such an extract, whereby the extract is prepared by extracting the leaves with boiling water followed by extracting the water-extract with an alcohol solvent, as well as removing the alcohol solvent (such as by lyophilization and/or centrifuging and drying/lyophilizing the extract) to obtain a dried extract preparation.

The cited reference discloses a therapeutic *Toona sinensis* leaf extract preparation which appears to be identical to the presently claimed extract preparation since the reference extract is prepared in a very similar manner to that instantly claimed/disclosed - i.e., it is prepared via boiling the leaves in 50% v/v alcohol/water, followed by centrifugation and lyophilization of the centrifuged supernatant (i.e., it would not seem that extracting firstly with water and secondly with alcohol would provide any measurable distinction with respect to the final extract product as compared to the reference extract product, since both *Toona sinensis* leaf preparations are subjected to the same extract solvents - having the same polarities - and, thus, the skilled artisan would reasonably expect that the same active ingredients would be contained within each of the

Art Unit: 1655

final lyophilized extract preparations). In addition, the reference dried extract is added to KBR buffer (which reads upon a pharmaceutical carrier) - see, e.g., page 386 under the headings *Preparation of leaf extract* and *Measurement of lipolysis*. Consequently, the claimed extract preparation appears to be anticipated by the reference extract preparation

In the alternative, even if the claimed extract preparation is not identical to the referenced extract preparation with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced extract preparation is likely to inherently possess the same characteristics of the claimed extract preparation particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed extract preparation would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Please note that the reference extract preparation would inherently read upon the instantly claimed intended-use form "adapted for use ... in treating ovarian or bladder cancer" (i.e., nothing would preclude its use as such).

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the USC 102/103 rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' extract preparation differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Art Unit: 1655

In addition, with respect to the USC 102/103 rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection (MPEP 2112).

Claim Rejections - 35 USC § 103

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (Am. J. Chinese Med., 2002), in view of Green (The Herbal Medicine-Maker's Handbook, 2000) and Luo et al. (Fitoterapia, 2000).

The claims are drawn to an extract from the leaves of *Toona sinensis* having anti-cancer activity (claimed as a product-by-process), a pharmaceutical composition comprising such an extract, and a preparatory process thereof whereby the extract is prepared by extracting the leaves with boiling water followed by extracting the water-extract with an alcohol solvent, as well as removing the alcohol solvent (such as by centrifuging - to form a supernatant, and drying the water and/or alcohol extract) to obtain a dried extract preparation.

Art Unit: 1655

Chang et al. beneficially teach an anti-cancer preparation comprising the centrifuged supernatant of a boiled water extract of *Toona sinensis* leaves (see, e.g., page 308 under the heading *Preparation of Extract of Toona sinensis Roemor*). Chang et al. do not teach further extraction of such an extract with alcohol, nor preparing a dried preparation thereof.

Green beneficially teaches that the two most common types of extraction solvents used to effectively extract therapeutically active agents from herbal plants are water and alcohol, and further that alcohol is reliably consistent in its actions as a solvent and preservative (see pages 80-81).

Luo et al. beneficially teach that therapeutic agents can be effectively extracted from *Toona sinensis* leaves via alcoholic extraction as well as drying the alcoholic extract preparation in vacuo (prior to isolation/purification of such bioactive compounds therefrom) - see, e.g., pages 494 - Experimental Sections 3.1 and 3.2.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to further include the step(s) of alcoholic extract and drying the alcoholic extract within the preparation method disclosed by Chang et al. based upon the beneficial teachings provided by the secondary references with respect to the conventional use of such preparatory extraction steps, as discussed above. Accordingly, the adjustment of these types of conventional working conditions (e.g., the addition of a commonly-employed alcoholic extraction step or a drying step to the extraction process disclosed by Chang et al., and/or preparing a pharmaceutical composition comprising the water extract preparation disclosed by Chang et al. - see, e.g., instant claim 19 - option (i)) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan within

Art Unit: 1655

the herbal arts. Please note that such an extract preparation would intrinsically read upon the instantly claimed intended-use form "adapted for use ... in treating ovarian or bladder cancer" (i.e., nothing would preclude its use as such).

Thus, the invention as a whole is prima facie obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate
Primary Examiner
Art Unit 1655